



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/801,517

03/16/2004

Xiaoyang Qi

0010872.0529639

4062

26874 7590 05/01/2008

FROST BROWN TODD, LLC
2200 PNC CENTER
201 E. FIFTH STREET
CINCINNATI, OH 45202

EXAMINER

SANG, HONG

ART UNIT

PAPER NUMBER

1643

NOTIFICATION DATE

DELIVERY MODE

05/01/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com
rgaunce@fbtlaw.com

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/801,517 | Applicant(s) QI, XIAOYANG | |
| | Examiner HONG SANG | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 9-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 44-57, 59-63 and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Qi

1. Applicant's response filed on 2/28/2008 is acknowledged.
2. Claims 1-65 are pending. New claims 58-65 have been added. Claims 9-43 have been withdrawn from further consideration as being drawn to non-elected inventions. Claims 1, 44 and 50 have been amended.

3. Newly submitted claims 58 and 64 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 58 and 64 are drawn to a process for the manufacture of a pharmaceutical composition comprising combining a composition comprising an inner leaflet component, and a prosaposin-related polypeptide, and treating the suspension of inner leaflet component and prosaposin-related polypeptide to form a nanovesicle. Inventions of Group I (originally elected) and inventions of new claims 58 and 64 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the pharmaceutical composition can be made by mixing nanoparticles of an inner leaflet component with a prosaposin polypeptide, as opposed to mixing two agents and treating the mixture to form nanoparticles. Searching the inventions of Group I and the inventions of new claims 58 and 64 together would impose serious search burden. The inventions of Group I and the inventions of new claims 58 and 64 have a separate

status in the art as shown by their different classifications (530/300 vs. 435/41).

Moreover, in the instant case, the search for a pharmaceutical composition and a method of making the pharmaceutical composition are not coextensive. The search for the inventions of new claims 58 and 64 would require a text search for the method steps. Moreover, even if the pharmaceutical composition was known, the method of making the pharmaceutical composition may be novel and unobvious in view of the active steps.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 58 and 64 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 1-8, 44-57, 59-63 and 65 are under examination. Due to restriction and species election, claims are examined to the extent that the inner leaflet component is phosphatidylserine, phosphatidylethanolamine, or a structure analog of phosphatidylserine wherein the structure analog of phosphatidylserine is dioleoylphosphatidylserine.

Objections Withdrawn

5. The objection to claim 50 because of a typographical error is withdrawn in view of applicant's amendment to the claims.

Rejections Withdrawn

6. The rejection to claims 44-49 under 35 U.S.C. 112, second paragraph because of lack antecedent basis is withdrawn in view of applicant's amendment to the claims.

Response to Arguments

Claim Rejections - 35 USC § 112, 1st paragraph (Written Description)

7. The rejection of claims 1-8, 50-57, and new claims 59-63 and 65 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The response states that the polypeptides of the present invention are not just any polypeptide, and they are limited by the functional characteristics of polypeptides retaining plasma membrane affinity. The response states that this function characteristics is a feature coupled with known correlation between this function and structure. The response states that it is well-known in the art that the plasma membrane affinity is contained in the fusogenic domain of SEQ ID NO.1 and 2, and this domain consisted of the first and second helical sequences (see Qi's publication, 3/11/2004).

Applicant's arguments have been carefully considered but are not persuasive. The amendment to the claims does not overcome the rejection. The claims have been amended to limit the polypeptide to an amino acid sequence set forth in SEQ ID NO.1 or 2, and SEQ ID NO.1 or 2 having one or more conservative substitutions. Therefore, the polypeptide is drawn to a genus of molecules. The phrase "one or more conservative substitution" encompasses one amino acid up to as many as all amino

Art Unit: 1643

acid substitutions at any positions within SEQ ID NO.1 or 2. There is a lack of written description regarding the structural characteristics of the claimed genus. The specification lacks written description regarding which amino acids and how many amino acids within the full length of SEQ ID NO.1 or 2 can be changed by conservative substitution such that the resulting variant has the claimed function (retaining plasma-membrane affinity). While the claims require all the variants to have the function of retaining plasma membrane affinity, the specification does not disclose the essential structural feature that is required for the claimed function. Although Qi's publication (3/11/2004) discloses that the plasma membrane affinity is contained in the fusogenic domain of SEQ ID NO.1 or 2, this information was published after the effective filing date of the instant application. Furthermore, claims 50-57 recite "a biologically active prosaposin-related polypeptide", which encompass any homologs and variant of prosaposin that are biologically active. No structural feature is recited in these claims. The specification fails to describe a common structure feature that is required by the members of the genus to perform the claimed function (retain plasma membrane affinity). Therefore, the specification provides no functional characteristics coupled to structural features. That is, the specification provides neither a representative number of the claimed polypeptide, nor does it provide a descriptive of structural features that are coupled to the functional features. Thus one of skill in the art would not be able to recognize that applicant was in possession of the invention as now claimed. Therefore, the rejection is deemed proper and maintained.

Claim Rejections - 35 USC § 112, 1st paragraph (Enablement)

8. The rejection of claims 1-8, 50-57, and new claims 59-63 and 65 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an agent comprising an anionic phospholipid, particularly phosphatidylserine and a prosaposin polypeptide of SEQ ID NO.1 or SEQ ID NO.2, does not reasonably provide enablement for an agent comprising any and all inner leaflet component, and any and all prosaposin-related polypeptide of an amino acid sequence that is at least 80% identical to SEQ ID NO.1 or 2 is maintained.

Applicants did not present arguments for this rejection; the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112, 1st paragraph (New Matter)

9. The rejection of claims 50-57 under 35 U.S.C. 112, first paragraph, because of new matter is maintained (it is noted that the rejection made to claims 1-8 and 44-49 is withdrawn in view of applicant's amendment to claims 1 and 44 to cancel the new matter).

The response states that claims 1 and 44 have now been amended to cancel this matter.

Because applicants did not cancel the new matter recited in claim 50, the rejection of claims 50-57 is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

10. The rejection of claims 1-8, 44-57, and new claims 59-63 and 65 under 35 U.S.C. 103(a) as being unpatentable over Vaccaro et al. (FEBS 1993, 336(1): 159-162) in view of the teachings of O'brien et al. (WO9503821A1), as evidenced by Vaccaro et al. (FEBS, 1994, 349: 181-186, IDS) is maintained.

The response states that the teachings of Vaccaro and O'Brien show forming liposomal vesicles and then adding saposin C to the formulation, resulting in a surface interaction of the protein with the vesicles. A lipid/saposin vesicle formed by this method will not function the same and will not exhibit anti-tumor activity as with the vesicles of the present invention. The claims are also amended to clarify this important feature showing that the prosaposin related polypeptide and the inner leaflet component are combined in an acidic buffer and then treated together to form a nanovesicle exhibiting anti-tumor activity.

Applicant's arguments have been carefully considered but are not persuasive. Vaccaro (1993) teaches mixing Sap C, and different amount of PS vesicles in 10 mM acetate buffer (pH 5.4) and incubating at 37°C for 30 min (see page 160, left column, section 2.5). The PS vesicles are small unilamellar vesicles (SUV) or large unilamellar vesicles (LUV) (see page 160, left column, section 2.7). As evidenced by Vaccaro (1994), the size of the nanoparticles formed between PS SUV and Sap C ranges from about 200-600 nm(see page 185, Figure 6B), between PS LUV and Sap C ranges between about 500-2000 nm (see page 185, Figure 6D) . Therefore, Vaccaro (1993)

Art Unit: 1643

teaches the claim limitation i.e. 10-800 nm recited in claim 1 and 0.01-1 μm (10-1000 nm).

Regarding the anti-tumor activity, the instant specification does not teach that only the nanovesicle form of PS/Sap C has antitumor activity. The nanoparticle form of PS/Sap C is only one embodiment of the claimed pharmaceutical composition (see page 21, paragraph [0071]). The specification teaches that combinations of these two compounds exhibit anti-tumor activity (see page 7, paragraph [0021]). The specification teaches that such composition typically comprise a prosaposin related polypeptide, an inner leaflet component, and a pharmaceutical acceptable carrier (see page 21, paragraph 0071], lines 4-5). The specification teaches that in an embodiment the prosaposin related polypeptide and the inner leaflet component form a nanovesicle, wherein the nanovesicle diameter is in the range of 10 to 10,000 nm (see page 21, paragraph [0071]). Example 6 discloses that administration of an agent comprising saposin C (10 mg/kg body weight) and DOPS (2 mg/kg body weight) to a nude mice bearing human squamous cell carcinoma xenografts inhibited tumor growth (see pages 33-34). Example 6 does not disclose that the agent is in nanoparticle form. Example 9 teaches treating Human SK-Mel-28 melanoma cells with mixtures of Saposin C and DOPS at different molar ratios, and these mixtures of Sap C and DOPS (note: no indication that the mixtures are in nanoparticle form) inhibit tumor cell growth *in vitro*. Therefore, the antitumor activity of the composition does not appear to depend on whether the composition is formulated in nanoparticle form. Moreover, the diameter of the prior art nanoparticle (200-2000 nm) falls within the range disclosed by the

specification (10-10,000 nm). In view of the teachings of the specification, the nanoparticles formed between PS SUV and Sap C and between PS LUV and Sap C taught by Vaccaro (1993) would have antitumor activity.

Claims 44-49, 59-63 and 65 are product by process claims. MPEP 2113 [R-1] states: PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). MPEP further states “The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979).

In the instant case, the product of Vaccaro appears the same as the claimed product for the reasons set forth above. Moreover, the claims do not define that manufacturing process steps impart any distinctive structural characteristics to the final

Art Unit: 1643

product compared to the product in the prior art, the patentability of the product cited in claims 44-49, 59-63 and 65 does not depend on its method of production.

11. The rejection of claims 1-8, 44-57, and new claims 59-63 and 65 under 35 U.S.C. 103(a) as being unpatentable over Vaccaro et al. (FEBS 1993, 336(1): 159-162) in view of the teachings of O'brien et al. (WO9503821A1), Vaccaro et al. (FEBS, 1994, 349: 181-186, IDS), and Egas et al. (J. Biol. Chem. 2000, 275(49): 38190-38196) is maintained.

The response states that the Declaration of Xiaoyang Qi states that Vaccaro and O'Brien merely show the formation of PS and PC liposomal vesicles and then adding SapC to the formulation, resulting in a surface interaction of the protein with the vesicles; a lipid/saposin vesicle formed by this method does not have the same structure and will not function the same and will not exhibit anti-tumor activity as with the vesicles of the present invention (also see Table 1 in response). The response states that the instant composition comprising a SapC-DOPS nanovesicle complex and not just a mixture of nanovesicles and SapC suspended in a carrier. The response states that Vaccaro (1994) shows that the liposome of Vaccaro (1993) are a much larger liposome vesicle (>2000 nm) that is not a nanovesicle having SapC integrated within its structure, and the instant nanovesicles are much smaller liposomes (about 200 nm or smaller) that exhibits anti-tumor activity.

Applicant's arguments have been carefully considered but are not persuasive. The Declaration of Xiaoyang Qi filed under Rule 1.132 is insufficient to overcome the

Art Unit: 1643

instant rejection. Vaccaro (1993) teaches mixing Sap C, and different amount of PS vesicles in 10 mM acetate buffer (pH 5.4) and incubating at 37°C for 30 min (see page 160, left column, section 2.5). The PS vesicles are small unilamellar vesicles (SUV) or large unilamellar vesicles (LUV) (see page 160, left column, section 2.7). As evidenced by Vaccaro (1994), the size of the nanoparticles formed between PS SUV and Sap C ranges from about 200-600 nm (see page 185, Figure 6B), between PS LUV and Sap C ranges between about 500-2000 nm (see page 185, Figure 6D). Therefore, Vaccaro (1993) teaches the claim limitation i.e. 10-800 nm recited in claim 1 and 0.01-1 μm (10-1000 nm).

Regarding the anti-tumor activity, the instant specification does not teach that only the nanovesicle form of PS/Sap C has antitumor activity. The nanoparticle form of PS/Sap C is only one embodiment of the claimed pharmaceutical composition (see page 21, paragraph [0071]). The specification teaches that combinations of these two compounds exhibit anti-tumor activity (see page 7, paragraph [0021]). The specification teaches that such composition typically comprise a prosaposin related polypeptide, an inner leaflet component, and a pharmaceutical acceptable carrier (see page 21, paragraph [0071], lines 4-5). The specification teaches that in an embodiment the prosaposin related polypeptide and the inner leaflet component form a nanovesicle, wherein the nanovesicle diameter is in the range of 10 to 10,000 nm (see page 21, paragraph [0071]). Example 6 discloses that administration of an agent comprising saposin C (10 mg/kg body weight) and DOPS (2 mg/kg body weight) to a nude mice bearing human squamous cell carcinoma xenografts inhibited tumor growth (see pages

33-34). Example 6 does not disclose that the agent is in nanoparticle form. Example 9 teaches treating Human SK-Mel-28 melanoma cells with mixtures of Saposin C and DOPS at different molar ratios, and these mixtures of Sap C and DOPS (note: no indication that the mixtures are in nanoparticle form) inhibit tumor cell growth *in vitro*. Therefore, the antitumor activity of the composition does not appear to depend on whether the composition is formulated in nanoparticle form. Moreover, the diameter of the prior art nanoparticle (200-2000 nm) falls within the range disclosed by the specification (10-10,000 nm). In view of the teachings of the specification, the nanoparticles formed between PS SUV and Sap C and between PS LUV and Sap C taught by Vaccaro (1993) would have antitumor activity.

The results of Table 1 and Figure 1 presented in the Declaration of Xiaoyang Qi have been carefully considered but are insufficient to overcome the rejection. As indicated above, the Examples 6 and 9 of the instant specification have clearly demonstrated that even a mixture of DOPS and Sap C is capable of inhibiting squamous cell carcinoma *in vivo* and melanoma cell proliferation *in vitro*, respectively (see Specification Examples 6 and 9, and page 37, Table 2). Therefore, the Declaration provided evidence that is inconsistent with the teachings of the specification. Moreover, the Declaration does not provide detailed information to enable one to compare side by side the results of the prior art nanoparticles and of the instant nanoparticles. For example, the size of the nanoparticles of the prior art was not described in the declaration. As such it provides insufficient evidence that the prior art nanoparticle is incapable of treating tumor.

Claims 44-49, 59-63 and 65 are product by process claims. MPEP 2113 [R-1] states: PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). MPEP further states “The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979).

In the instant case, the product of Vaccaro appears the same as the claimed product for the reasons set forth above. Moreover, the claims do not define that manufacturing process steps impart any distinctive structural characteristics to the final product compared to the product in the prior art, the patentability of the product cited in claims 44-49, 59-63 and 65 does not depend on its method of production.

Double Patenting

12. The rejection of claims 1-3, 44-47, 50-52, and new claims 59-61 and 65 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 16, 17, 21 and 22 of U.S. Patent No. 6,872,406 in view of Vaccaro et al. (FEBS Lett. 1994, 349: 181-186, IDS) is maintained.

The response states a Terminal Disclaimer will be filed if conflicting claims are issued.

Since no Terminal Disclaimer has been filed, the rejection is maintained.

Double Patenting

13. The provisional rejection of claims 1-3, 44-47, 50-52 and new claims 59-61 and 65 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16, 17, 21 and 22 of copending Application No. 10/967,921 in view of Vaccaro et al. (FEBS Lett. 1994, 349: 181-186, IDS) is maintained.

The response states a Terminal Disclaimer will be filed if conflicting claims are issued.

Since no Terminal Disclaimer has been filed, the rejection is maintained.

New Grounds of Objections and Rejections

Claim Objections

14. Claims 44-49, 59-63, and 65 are objected to because of the following informalities: the claims depend from a non-elected invention i.e. claims 58 and 64. Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

15 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the biologically active portion of prosaposin polypeptide". There is insufficient antecedent basis for this limitation.

Claim Rejections - 35 USC § 112, 1st paragraph

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 1-8, 44-49, 63, and 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **new matter** rejection.

The phrases "wherein the nanovesicle has an average diameter in the range of 10-800 nm" recited in claim 1, "wherein the nanovesicle has a diameter in the range 0.01 to 1 μ m" recited in claim 63, and "wherein the nanovesicle formed has a diameter

in the range 10-800 nm and exhibits anti-tumor activity” recited in claims 44-49 and 65 (limitation from claim 64) are considered new matter since the specification, drawings and claims as filed disclose only the range of 0.01 to 10 μm , 0.1 to 1 μm , and 0.1 to 0.5 μm . There is no clear support for the range of 0.01-1 μm , and 10-800 nm.

If applicant believes that support for the above-mentioned phrases or terms is present in the specification, claims or drawing as originally filed, applicant must, in responding to this action, point out with particularity, where such support may be found.

Applicant is required to cancel the new matter in the reply to this Office Action.

Conclusion

19. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1643

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643
4/22/08

/Christopher H Yaen/
Primary Examiner, Art Unit 1643